REDACTED DOCUMENTS RELATED TO DOCKET 7351

7351 - Defendants' Motion and Memorandum in Support of Motion for Partial Summary Judgment of Plaintiffs Doris and Alfred Jones's Claims - Filed Redacted

7352 - Defendants' Separate Statement of Facts in Support of Motion for Partial Summary Judgment of Plaintiffs Doris and Alfred Jones's Claims - Filed Redacted

Exhibit A - Filed Redacted

Exhibit B - Filed Redacted

Exhibit D - Filed Redacted

Exhibit E - Filed Redacted

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7351 - Defendants' Motion and Memorandum in Support of Motion for Partial Summary Judgment of Plaintiffs Doris and Alfred Jones's Claims - Filed Redacted

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, DORIS JONES and ALFRED JONES, a married couple, Plaintiffs, v. C. R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Defendants.	No. 2:15-MD-02641-DGC **DEFENDANTS' MOTION AND MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT OF PLAINTIFFS DORIS AND ALFRED JONES'S CLAIMS** (Assigned to the Honorable David G. Campbell) **(Oral Argument Requested)**

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MOTION

Pursuant to Fed. R. Civ. P. 56(c), Local Rule 56.1, and Case Management Order No. 23 (Doc. 5770), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully move this Court for partial summary judgment as to certain of Plaintiff Doris Jones's product liability claims (Counts II, VII, VIII, IX, XII) and her claim for punitive damages as alleged in Plaintiff's Short Form Complaint (2:16-cv-00782-DGC, Doc. 1). Plaintiffs have withdrawn claims for manufacturing defect (Counts I and V), Negligent Failure to Recall/Retrofit (Count VI), Breach of Express Warranty (Count X), and Breach of Implied Warranty (Count XI). For the reasons stated below, Bard is entitled to judgment as a matter of law as to certain other claims asserted by the plaintiff.

This motion is supported by Defendants' Memorandum of Points and Authorities and Separate Statement of Facts ("SSOF") which are filed herewith.

MEMORANDUM OF POINTS AND AUTHORITIES

I. Introduction.

Plaintiff Doris Jones brings this product liability action for damages she claims to have suffered as a result of complications allegedly experienced related to a Bard Eclipse® inferior vena cava filter, a prescription medical device that was placed in her inferior vena cava ("IVC") after she suffered from recurrent deep vein thrombosis ("DVT"), and before undergoing surgery for afferent loop syndrome, to help prevent a potentially life-threatening pulmonary embolism. [redacted] (the "Filter"). Plaintiff claims that the Filter was defective because, [redacted] Notably, fracture is a well-known and accepted potential complication with all IVC filters (including with the Filter), given the life-saving nature of these devices. Indeed, Ms. Jones's implanting physician testified that he was well-aware of these potential complications before placing the Filter, and did not recall ever reading the Filter's Instructions for Use ("IFU") because he was already familiar with the risks.

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Bard moves for partial summary judgment under Federal Rule of Civil Procedure 56 on the following grounds:[1]

A. Plaintiff's failure-to-warn (Counts II, VII) and misrepresentation (Counts VIII, XII) claims fail because Plaintiff has failed to provide any evidence that the implanting physician ever read the Eclipse IFU. Furthermore, Bard provided adequate warnings of the complications experienced by Plaintiff and any alleged failure to warn by Bard was not the proximate cause of Plaintiff's injuries.

B. Plaintiff's consumer fraud claim (Count XIV) fails because Plaintiff has not provided any evidence that that the implanting physician received any misrepresentation or relied on any misrepresentation.

C. Plaintiff's negligence *per se* claim (Count IX) fails because Plaintiff has not provided any evidence that Bard violated a state safety statute and any alleged violation of the FDCA would be preempted by federal law.

D. Plaintiff's punitive damages claim fails because there is no evidence that such are warranted.

II. Statement of Undisputed Facts.

Plaintiff [redacted] (SSOF ¶ 1.) The Filter is sold to medical facilities, not directly to doctors or patients. (*Id.* at ¶ 2.)

[redacted] (*Id.* at ¶ 3.)

[redacted] (*Id.*) [redacted]

[1] Bard met and conferred extensively with counsel for Ms. Jones prior to filing this motion. Counsel represented that they were going to continue pursuing all of the claims addressed in this motion.

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[redacted] (*Id.* at ¶ 4.) [redacted] (*Id.* at ¶ 5.) [redacted] (*Id.* at ¶ 6.) [redacted] (*Id.* at ¶ 7.) However, [redacted] (*Id.*) [redacted] (*Id.* at ¶ 8.) [redacted] (*Id.* at ¶ 9.) [redacted]. (*Id.* at ¶ 10.) [redacted] (*Id.*)

Dr. Avino testified that he does not recall ever reading the IFU. (*Id.* at ¶ 12.) However, he explained that he was generally familiar with IVC filter IFUs, the risks inherent with all IVC filters such as fracture, migration, perforation, and tilt, and began implanting IVC filters during his residency, 20 years before he implanted Ms. Jones' filter. (*Id.* at ¶ 13.) Although there is no evidence that Dr. Avino read the IFU, which was reviewed by the FDA as a part of the clearance process, it specifically identifies fracture and embolization as known risks of the Filter. (*Id.* at ¶ 14.)

Five years later, [redacted] (*Id.* at ¶ 17.) [redacted]. (*Id.*) [redacted] (*Id.* at ¶ 18.) [redacted]

[redacted] (*Id.* at ¶ 19.) [redacted]. (*Id.* at ¶ 20.) [redacted] (*Id.*) [redacted] (*Id.*)

III. Summary Judgment Standard.

Summary judgment is appropriate upon showing that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see Jesinger v. Nev. Fed. Credit Union*, 24 F.3d 1127, 1130 (9th Cir. 1994). Where the moving party will have the burden of proof at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. *Southern Calif. Gas. Co. v. City of Santa Ana*, 336 F.3d 885, 888 (9th Cir. 2003).

IV. Georgia Substantive Law Applies.

Georgia substantive law governs Plaintiff's common-law claims. Although Plaintiff filed her complaint directly in the MDL, she identified Georgia in her Short Form Complaint as the forum in which venue would be proper absent direct filing, (2:16-cv-00782-DGC, Doc. 1), so Georgia's conflict-of-law rules apply. (*See* Doc. 1485). Georgia follows the *lex loci delicti* doctrine, which applies the substantive law of the place of injury. *See Coon v. Med. Ctr., Inc.*, 300 Ga. 722, 730, 797 S.E.2d 828, 834 (2017). The place of injury here is Georgia because "at least a substantial amount, if not all, of the injuries allegedly caused by the [filter's] alleged defects occurred in Georgia. Therefore, because 'the last event . . . necessary to make [Defendants] liable for the alleged tort[s]' likely occurred in Georgia, the Court applies Georgia law." *See Schmidt v. C. R. Bard, Inc.*, No. 6:14-CV-62, 2014 WL 5149175, at *2 (S.D. Ga. Oct. 14, 2014) (applying Georgia substantive law under *lex loci delicti* despite plaintiff being implanted with medical device in Michigan).

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V. Argument and Citation of Authority.

A. Plaintiff's Failure-to-Warn (Counts II, VI) and Misrepresentation (Counts VIII, XII) Claims Fail Because There Is No Evidence Dr. Avino Read the IFU, and Bard Provided Adequate Warnings and/or Any Alleged Failure to Warn Could Not Be the Proximate Cause of Plaintiff's Injuries.

1. Plaintiff Has Failed to Provide Any Evidence That Dr. Avino Read the IFU.

Plaintiff's failure-to-warn and misrepresentation claims fail[2] because Ms. Jones's implanting physician, Dr. Avino, did not read the IFU. It is well settled under Georgia law that "[u]nder the learned intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer. The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ prescription medication [or medical devices] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities." *McCombs v. Synthes*, 277 Ga. 252, 253, 587 S.E.2d 594 (2003) (internal citations omitted); *see also*, *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1277–81, 1281 (11th Cir. 2002) (per curiam).

"[F]ailure to read instructions or printed warnings will prevent a plaintiff from recovering on a claim grounded on failure to provide adequate warning of the product's potential risk." *Wilson Foods Corp. v. Turner*, 218 Ga. App. 74, 75, 460 S.E.2d 532, 534 (1995). Here, Plaintiff cannot prove that any warning inadequacy was the proximate cause of her injuries because she cannot prove that Dr. Avino ever read the IFU:

Q. Do you know if you ever read the IFU for the Eclipse IVC filter?

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[2] Under Georgia law, there are "no misrepresentation claims for products liability distinct from failure to warn claims." *Brazil v. Janssen Research & Dev. LLC*, No. 4:15-CV-0204-HLM, 2016 WL 4844442, at *11 (N.D. Ga. Mar. 24, 2016). Accordingly, Plaintiff's negligent and fraudulent misrepresentation claims (Counts VIII, XII) "collapse into the failure to warn claims," and fail for the same reasons. *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1357 (N.D. Ga. 2008).

A. Not that I recall.

(SSOF, ¶ 12.) As a result, Plaintiff's failure to warn claim should be dismissed. *See In re Wright Med. Tech. Inc., Conserve Hip Implant Prod. Liab. Litig.*, 127 F. Supp. 3d 1306, 1360 (N.D. Ga. 2015) ("[The implanting physician] does not recall reading a product insert, and its warnings, that accompanied any hip replacement device he has implanted. As a result of his personal practices, the undisputed evidence is that [the implanting physician] did not and would not have read the insert warnings that were provided with the device implanted to replace Plaintiff's right hip. As a result, the evidence here does not support a failure to warn claim based on the warning provided for the implant at issue in this case, even if the warning was defective.") (applying Utah law but citing various jurisdictions in which a prescribing physician's failure to read the product warning broke the chain of causation) (citations omitted).

Moreover, Plaintiff's failure to warn claim lacks proximate causation for a second, independent reason: Dr. Avino had actual knowledge of the risk of fracture. Instead of reading the Eclipse IFU, Dr. Avino was "generally familiar with IVC filter IFUs, if they warn of things like fractures, migration, perforation, tilt; complications like that," and began implanting IVC filters during his residency, 20 years before he implanted Ms. Jones' filter. (SSOF, ¶ 13.) *See Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1363 (N.D. Ga. 1999) (concluding that "[r]egardless of the sufficiency or insufficiency of the warnings at issue here, Plaintiff still cannot recover. Where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that the learned intermediary doctrine applies or that the causal link is broken and the plaintiff cannot recover."); *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1277–78, 1281 (11th Cir. 2002) (per curiam) (finding that manufacturer adequately warned doctors and nurses of risks of third-party activation of morphine pump because evidence demonstrated the doctors and nurses all had actual knowledge of risk).

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2. Even If Dr. Avino Read the IFU, the Warning Was Adequate Because It Warned of the Precise Risk Experienced by Plaintiff.

Under the learned intermediary doctrine, a manufacturer discharges its duty to warn by apprising the prescribing physician of potential dangers that may result from the device's use. *Hawkins*, 147 Ga. App. at 483, 249 S.E.2d at 288; *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 (11th Cir. 2002) ("Ellis also suggests that, even if the learned intermediary rule applies, there was a jury issue regarding the sufficiency of the warnings given by the defendants to the learned intermediaries in this case. We disagree. As the district court noted, defendants presented evidence that, through Bimeco, it warned the physicians and nurses at GBMC that only the patient should press the activation button unless a doctor ordered otherwise."). If the warning provided to the learned intermediary is adequate, the plaintiff cannot recover. *Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010).

Here, Bard had a duty to warn Dr. Avino of the risks of its use. Even though Dr. Avino could not recall ever reading the Eclipse IFU, it contains specific warnings regarding the risk of filter fracture, [redacted] Under the bolded heading "**Warnings**," the IFU reads:

> - Filter fracture is a known complication of vena cava filters. There have been reports of embolization of vena cava filter fragments resulting in retrieval of the fragment using endovascular and/or surgical techniques. Most cases of filter fracture, however, have been reported without any adverse clinical sequelae.

(SSOF, ¶ 14.) This warning is repeated under the bolded heading "**Potential Complications**", which also adds that:

> **All of the above complications have been associated with serious adverse events such as medical intervention or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ration for a patient who is at risk of pulmonary embolism without intervention.**

(*Id.* at ¶ 15.) (emphasis in original). Furthermore, the "Clinical Experience" section notes the number of fracture observed during the clinical study of one hundred patients. (*Id.* at ¶

16.). Because the IFU contained warnings regarding the relevant risks of using the Filter, Bard's warnings were adequate. *See Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1283 (11th Cir. 2002); *Presto v. Sandoz Pharm. Corp.*, 226 Ga. App. 547, 548, 487 S.E.2d 70, 73 (1997) ("a warning as to possible danger in [the prescription product's] use to the prescribing physician is sufficient").

Moreover, Bard cannot be liable for failure to warn of the complications with the Filter experienced by Ms. Jones because those complications are well-known by medical professionals. Where a product is sold to a particular group or profession, the manufacturer is not required to warn against risks generally known to such group or profession. *Exxon Corporation v. Jones*, 209 Ga. App. 373, 375, 433 S.E.2d 350 (1993) (quoting *Eyster v. Borg-Warner Corp.*, 131 Ga. App. 702, 704, 206 S.E.2d 668 (1974)); *see Ellis*, 311 F.3d at 1277–78, 1281. Accordingly, even had the IFU not provided the necessary warnings, which Bard denies, Bard could not be liable for failure to warn of the complications experienced by Ms. Jones because they were widely known, and well-documented, by the medical community. (SSOF at ¶¶ 21-23.) Indeed, Plaintiff's expert acknowledges that *all* IVC filters are known to have complications, including filter fracture, migration, tilt, and perforation and Plaintiff's biomedical engineering expert testified it is impossible to design an IVC filter that never tilts, fractures, migrates, or perforates. (*Id.*) Because the relevant risks involved in implanting the Filter were well-documented and well-known to medical professionals, Bard cannot be liable for any failure to warn of those risks. *See Ellis*, 311 F.3d at 1279-80.

Plaintiff likely will assert that Bard was obligated to warn that the Filter may have been more likely to fail than other IVC filters. However, Bard can find no Georgia law creating a duty on a manufacturer to provide comparative rates of complication for its product to other similar products on the market. Indeed, Georgia law does not require a manufacturer to provide comparative rates of complication for its products. *See Hoffman v. AC&S, Inc.*, 248 Ga. App. 608, 610, 548 S.E.2d 379, 382 (2001) (noting under Georgia law, "a manufacturer has the absolute right" to have his strict liability for injuries

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adjudged on the basis of "his own marketed product and not that of someone else."); *see also Dixie Grp., Inc. v. Shaw Indus. Grp., Inc.*, 303 Ga. App. 459, 463, 693 S.E.2d 888, 892 (2010) (same). And, courts from other jurisdictions that have addressed the issue have found that pharmaceutical and medical-device manufacturers have no such duty to warn. *See, e.g., Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 291–92 (6th Cir. 2015) (affirming summary judgment on failure to warn claim where the lower court rejected the plaintiff's argument that the product labeling did not warn that the risk of stroke for the birth control at issue was higher than with other birth control products); *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6th Cir. 1990) ("The manufacturer is obligated to make a reasonable disclosure of all the risks inherent in its own drug . . . . It is not obligated to provide a comparison of its drug with others").[3] Likely for this reason, Bard could find no IVC filter manufacturer that provides comparative rates in the instructions for use that it provides to doctors. *See* Competitor IFUs (not including any comparative rate information), attached as Exhibit A. Accordingly, summary judgment is

[3] *See also Smith ex rel. Smith v. Wyeth Labs., Inc.*, No. CIV.A. 84-2002, 1986 WL 720792, at *9–10 (S.D. W. Va. Aug. 21, 1986) (rejecting argument that defendants had a duty to warn of adverse reaction rates as compared to competitor products, noting there is "no authority for the proposition that a drug manufacturer has a duty to warn prescribing physicians of the rate of adverse reactions" and "no authority for [the plaintiffs'] argument that a drug manufacturer may be required to represent that other drugs with similar effects are safer," and "[a]s a practical matter, this would extremely difficult, perhaps impossible . . . ."); *Percival v. Am. Cyanamid Co.*, 689 F. Supp. 1060, 1064 (W.D. Okla. 1987) (finding defendant's warning label on its DTP vaccine adequate as a matter of law and quoting Smith); *Pluto v. Searle Lab.*, 690 N.E.2d 619, 621 (Ill. App. Ct. 1997) (finding a pharmaceutical manufacturer "is under no duty to provide information on other products in the marketplace"); *Cowart v. Avondale Indus., Inc.*, 792 So. 2d 73, 77 (La. Ct. App. 2001), writ denied 805 So. 2d 211 (rejecting plaintiff's argument that defendant manufacturer owed a duty to plaintiff to make him aware of safer alternative products and reversing lower court's denial of summary judgment); *Hain v. Johnson & Johnson* (N.J. Super. Ct. June 13, 2013) ATL-L-8568-11 MT (granting summary judgment to defendant pharmaceutical manufacturer and rejecting plaintiff's argument that label was inadequate due to its failure to disclose that studies showed higher tendon toxicity in defendant's drug compared to other like drugs); *cf. McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 405 (S.D.N.Y. 2014) ("courts have refused to graft onto the adequacy standard a requirement that a package insert must include specific adverse event frequencies"); *Pauley v. Bayer Corp.*, No. 2681 EDA 2005, 2009 WL 1654592, at *3 (Pa. Super. Ct. June 12, 2009) (affirming lower court's ruling that no evidence should be presented to jury based on either AER data or comparative AER data that adverse events occurred more frequently with defendant's drug than with other drugs "because AERs are generally unreliable and not scientifically verified").

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appropriate on Plaintiff's failure to warn claim.

B. Plaintiff's Consumer Fraud Claim (Count XIV) Fails Because She Cannot Prove Any of the Required Elements.

In her short form complaint, Plaintiff alleges "Violations of Applicable Georgia Law Prohibiting Consumer Fraud and Unfair and Deceptive Trade Practices." Although Plaintiffs' Master Complaint does not reference the applicable Georgia statute, "[t]o prevail on a private claim under the [Fair Business Practices] Act, a plaintiff must establish three elements: violation of the Act, causation, and injury. But an FBPA plaintiff must also comply with the ante litem requirement of OCGA § 10–1–399(b)." *Alvear v. Sandy Springs Toyota, Inc.*, 332 Ga. App. 798, 803, 775 S.E.2d 172, 177 (2015) (internal quotations omitted). Plaintiff has put forth no evidence of any misrepresentation made to Dr. Avino, any reliance on a misrepresentation by Dr. Avino, or that she has met any of the other requirements, such as ante litem notice, for a FBPA claim. As such, her claim should be dismissed. *Brazil v. Janssen Research & Dev. LLC*, No. 4:15-CV-0204-HLM, 2016 WL 4844442, at *11 (N.D. Ga. Mar. 24, 2016) ("Once again, Plaintiff's allegations amount merely to restating the elements of the cause of action without any factual support. Plaintiff pleads merely that Defendants violated the consumer protection laws through the use of false and misleading misrepresentations. In doing so, Plaintiff provides no factual support for that legal conclusion.").

C. Plaintiff's Negligence *Per Se* Claim (Count IX) Fails Because Plaintiff Has Failed to Provide Any Evidence that Bard Violated a State Safety Statute and Any Alleged Violation of the FDCA Would Be Preempted By Federal Law.

Under Georgia law, "a defendant is considered negligent per se based upon violation of a statute if there is evidence that the defendant violated the statute, the injured person was in the class the statute was intended to protect, the injured person suffered the type of harm the statute intended to guard against, and the alleged negligence per se proximately caused the injuries." *Leonard v. Medtronic, Inc.*, No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19, 2011). However, "a private litigant cannot

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bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist." *Id.* (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). This is because "no privatswze right of action exists for a violation of the FDCA." *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001); 21 U.S.C. § 337(a).

Plaintiff has failed to allege or produce evidence showing that Bard violated any state safety statute. Instead, Plaintiff alleges that Bard violated the FDCA by marketing an adulterated and misbranded device. Plaintiff's "claim of negligence per se would not exist prior to the enactment of the FDCA misbranding and adulteration laws because the claim only alleges violation of that law." *Leonard*, 2011 WL 3652311, at *8. To the extent that Plaintiff's claim is only founded upon an alleged violation of the FDCA or related FDA regulations, such claim should be impliedly preempted. *Id.* (finding negligence per se claim impliedly preempted by § 337(a) because "Plaintiffs cannot create a private right of action under the guise of a state law claim."). Since Plaintiff has provided no evidence of a violation of a state safety statute, and reliance on any alleged violation of the FDCA would be impliedly preempted by federal law, Bard is entitled to summary judgment.

D. Plaintiff Has Offered No Evidence Sufficient To Bring a Punitive Damages Claim.

Plaintiff's punitive damages claim is without merit under Georgia law and must be dismissed. As a preliminary matter, under Georgia law, a plaintiff has no right to punitive damages, which are only assessed in extreme cases. *Roberts v. Forte Hotels, Inc.*, 227 Ga. App. 471, 472, 489 S.E.2d 540, 542 (1997). To authorize punitive damages, Plaintiff must show clear and convincing evidence of "willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of a conscious indifference to the consequences" of the tortious act. O.C.G.A. § 51-12-5.1(b). "Conscious indifference to consequences means an intentional disregard of the rights of

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another, knowingly or willfully;" indeed, under Georgia law, even clear and convincing evidence of gross negligence will not support an award of punitive damages. *COMCAST Corp. v. Warren*, 286 Ga. App. 835, 838-39, 650 S.E.2d 307, 311 (2007).

Moreover, a manufacturer's "compliance with county, state, and federal regulations is not the type of behavior which supports an award of punitive damages," and, "as a general rule," punitive damages are "improper where a defendant [in a products liability case] has adhered to . . . safety regulations." *Stone Man, Inc. v. Green*, 263 Ga. 470, 472, 435 S.E.2d 205, 206 (1993). "This is because 'such compliance does tend to show that there is no clear and convincing evidence of 'willful misconduct, malice, fraud, oppression, or that entire want of care which would raise the presumption of [a] conscious indifference to [the] consequences.'" *Barger v. Garden Way, Inc.*, 231 Ga. App. 723, 728, 499 S.E.2d 737, 743 (1998). While compliance with safety regulations does not automatically preclude punitive damages if "there is other evidence showing culpable behavior," to survive summary judgment, Plaintiff still "must present some evidence of 'willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences.'" *Edwards v. Ethicon, Inc.*, 30 F. Supp. 3d 554, 564 (S.D. W. Va. 2014) (citations omitted) (applying Georgia law and granting summary judgment on punitive damages claim).

Here, punitive damages are not warranted because there is no evidence that Bard acted with the malice, fraud, wantonness, oppression, or entire want of care necessary to sustain an award of punitive damages. O.C.G.A. § 51-12-5.1(b). Instead, Bard complied with applicable FDA regulations in bringing the Filter to market, resulting in the Filter being cleared by the FDA through the 510(k) process outlined in the FDCA for retrievable use on January 14, 2010. (SSOF, ¶ 24); *see* 21 U.S.C. § 360e(b)(1)(B) (establishing 510(k) clearance); 21 C.F.R. 807.87 (outlining process for 510(k) clearance application); *see generally* Defendants' Motion for Summary Judgment Regarding Preemption (Doc. 5396). Bard also complied with applicable regulations in the Filter's labeling. Furthermore, there is no evidence in this case that Bard intentionally disregarded

Plaintiff's rights, which is necessary to show a "conscious indifference to consequences," *COMCAST*, 286 Ga. App. at 839, 650 S.E.2d at 311, or that Bard specifically acted with the purpose of causing damage and loss. Because Plaintiff cannot offer evidence that Bard acted deliberately and with malice with regard to Plaintiff, or with an entire want of care, her punitive damages claim must fail.

VI. Conclusion.

For these reasons, Bard respectfully requests that this Court grant Bard's Motion for Partial Summary Judgment.

RESPECTFULLY SUBMITTED this 28th day of August, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
Richard B. North, Jr.

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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, DORIS JONES and ALFRED JONES, a married couple, Plaintiffs, v. C. R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Defendants.	No. 2:15-MD-02641-DGC **DEFENDANTS' SEPARATE STATEMENT OF FACTS IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT AS TO PLAINTIFFS DORIS AND ALFRED JONES'S CLAIMS** (Assigned to the Honorable David G. Campbell)

Pursuant to Fed. R. Civ. P. 56(c), Local Rule 56.1(a), and Case Management Order No. 53 (Doc. 5770), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully submit this Separate Statement of Facts in Support of Motion for Summary Judgment as to Plaintiffs Doris and Alfred Jones's Claims.

1. Plaintiff Doris Jones [redacted] (the "Filter") [redacted] (Ex. A, Plaintiff Fact Sheet of Plaintiff Doris Jones (hereinafter "PFS"), at §§ II.2(a), II.3; Ex. B, Selected Plaintiff Medical Records, at JONESD_MUMC_MDR01287-88).

2. The Filter is not sold directly to patients. (Ex. C, Eclipse Filter Instructions for Use (the "Eclipse IFU") at page 1.)

3. [redacted]. (Ex. B, Selected Plaintiff Medical Records, at JONESD_UFHJ_MDR00266).

4. [redacted] (*Id.* at JONESD_MUMC_MDR01548-1549).

5. [redacted] (*Id.* at JONESD_MUMC_MDR00452-456).

6. [redacted] (*Id.* at JONESD_MUMC_MDR00723).

7. [redacted] However, [redacted]. (*Id.* at JONESD_MUMC_MDR01287-88).

8. [redacted]

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[redacted] (Ex. D, March 23, 2017, Deposition Transcript of Anthony Avino, M.D. ("Avino Dep. Tr.") at 110:22 to 113:25.)

9. [redacted] (Ex. B, Selected Plaintiff Medical Records, at JONESD_MUMC_MDR01287-88).

10. Dr. Avino testified that [redacted] (*Id.* at ¶ #). [redacted] (Ex. D, Avino Dep. Tr. at 54:14 to 55:8.)

11. [redacted]. (Ex. B, Selected Plaintiff Medical Records, at JONESD_MUMC_MDR01287-88).

12. Dr. Avino testified that he does not recall ever reading the IFU. (Ex. D, Avino Dep. Tr. at 47:21-23)

13. Dr. Avino was "generally familiar with IVC filter IFUs, if they warn of things like fractures, migration, perforation, tilt; complications like that," and began implanting IVC filters during his residency, 20 years before he implanted Ms. Jones' filter. (*Id*. at 8:16-23; 29:15-25; 48:2-7.)

14. The Eclipse IFU applicable in August 2010 (when Plaintiff received her Filter) included the following warnings:

- Under the bolded heading "**Warnings**" the Eclipse® IFU reads as follows:

  - Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.

(Ex. C, Eclipse IFU at p. 2.)

//

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15. This warning is repeated under the bolded heading "**Potential Complications**", which also adds that:

* * *

> **All of the above complications have been associated with serious adverse events such as medical intervention and/or death. There have been reports of complications including death, associated with the use of vena cava filters in morbidly obese patients. The risk/benefit ratio of any of these complications should be weighed against the inherent risk/benefit ration for a patient who is at risk of pulmonary embolism without intervention.**

(*Id*. at pp. 2-3.)

16. The "Clinical Experience" section notes the number of fracture observed during the clinical study of one hundred patients. (*Id*. at p. 4.)

17. [redacted] (Ex. B, Selected Plaintiff Medical Records, at JONESD_MUMC_MDR00007-00011.)

18. [redacted] (*Id.* at JONESD_MUMC_MDR00114-115.)

19. [redacted] (*Id*.; *Id*. at JONESD_MUMC_MDR00065.)

20. [redacted] (*Id.* at JONESD_MUMC_MDR00004-6).

21. Plaintiff's expert, Dr. Muehrcke, acknowledges that all IVC filters are known to have potential complications, including filter fracture, migration, tilt, and perforation. (Ex. E, July 24, 2017 Dr. Derek Muehrcke Deposition Transcript ("Muehrcke Dep. Tr."), at 55-22 to 57:9.)

22. The plaintiffs' engineering expert testified that he is not aware of any IVC filter that has been developed that is complication free, (Ex. F, July 19, 2016 Dr. Robert McMeeking Deposition Transcript, at 133:19 to 134:19), nor is he aware of any implantable medical device that is one hundred percent complication free. (Ex. G, April

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22, 2014 Dr. Robert McMeeking Deposition Transcript, at 149:9-13).

23. As the plaintiffs' experts recognize, "[e]very filter can have a complication;" therefore, it would be "unrealistic" for a physician implanting a Bard IVC filter to expect that the filter would never migrate, tilt, perforate, or fracture. (Ex. E, Muehrcke Dep. Tr. at 102:16 to 103:2).

24. The Filter was cleared by the FDA for retrievable use on January 14, 2010, through the 510(k) process outlined in the Food, Drug, and Cosmetic Act. (Ex. H, August 29, 2005 FDA Clearance Letter[1]).

RESPECTFULLY SUBMITTED this 28th day of August, 2017.

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[1] Available at https://www.accessdata.fda.gov/cdrh_docs/pdf9/K093659.pdf, last accessed August 25, 2017.

REDACTED DOCUMENTS RELATED TO DOCKET 7351

Exhibit A - Filed Redacted

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

MDL No. 2641
In Re Bard IVC Filter Products Liability Litigation

PLAINTIFF FACT SHEET

Each plaintiff who allegedly suffered injury as a result of a Bard Inferior Vena Cava Filter must complete the following Plaintiff Fact Sheet ("Plaintiff Fact Sheet"). In completing this Fact Sheet, you are **under oath and must answer every question.** You must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details as requested, please provide as much information as you can and then state that your answer is incomplete and explain why, as appropriate. If you select an "I Don't Know" answer, please state all that you do know about that subject. If any information you need to complete any part of the Fact Sheet is in the possession of your attorney, please consult with your attorney so that you can fully and accurately respond to the questions set out below. If you are completing the Fact Sheet for someone who cannot complete the Fact Sheet for himself/herself, please answer as completely as you can.

The Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and responses to requests for production pursuant to Fed. R. Civ. P. 34 and will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. Therefore, you must supplement your responses if you learn that they are incomplete or incorrect in any material respect. The questions and requests for production of documents contained in this Fact Sheet are non-objectionable and shall be answered without objection. This Fact Sheet shall not preclude Bard Defendants from seeking additional documents and information on a reasonable, case-by-case basis, pursuant to the Federal Rules of Civil Procedure and as permitted by the applicable Case Management Order.

In filling out this form, "healthcare provider" shall mean any medical provider, doctor, physician, surgeon, pharmacist, hospital, clinic, medical center, physician's office, infirmary, medical/diagnostic laboratory, or any other facility that provides medical care or advice, along with any pharmacy, x-ray department, radiology department, laboratory, physical therapist/physical therapy department, rehabilitation specialist, chiropractor, or other persons or entities involved in your diagnosis, care and/or treatment.

In filling out this form, the terms "You" or "Your" refer to the person who received a Bard Inferior Vena Cava Filter manufactured and/or distributed by C. R. Bard, Inc. or Bard Peripheral Vascular, Inc. ("Bard Defendants") and who is identified in Question 1(a) below.

To the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary, Information provided by Plaintiff will only

be used for the purposes related to this litigation and may be disclosed only as permitted under the protective order in this litigation.

I. BACKGROUND INFORMATION

1. Please state:

   (a) Full name of the person who received the Bard inferior vena cava filter, including maiden name: Doris Yvette Singleton-Jones

   (b) List all names by which you have ever been known, if different from that listed in 1(a): Doris Yvette Singleton

   (c) Full name of the person completing this form, if different from the person listed in 1(a) above, and the relationship of the person completing this form to the person listed in 1(a) above: Doris Yvette Singleton-Jones and Alfred Jones

   (d) The name and address of your primary attorney:

   Paul L. Stoller
   Gallagher & Kennedy PA
   2575 E. Camelback Road, Phoenix, AZ 85016
   paul.stoller@gknet.com / 602-530-8000

   (e) When did you first retain an attorney to represent you in your lawsuit against Bard? October 5, 2015

2. Your Social Security Number: [redacted]

3. Your Date of Birth: [redacted]

4. Your current residential address:
[redacted]

5. If you have lived at this address for less than 10 years, provide each of your prior residential addresses from 2000 to the present:

Prior Residential Address	Dates You Lived At This Address

6. Have you ever been married? ☒Yes ☐ No

If yes, provide the names and addresses of each spouse and the inclusive dates of your marriage to each person:

[redacted]

7. Do you have children? ☒Yes ☐ No

If Yes, please provide the following information with respect to each child:

Full Name of Child	Date of Birth	Home Address	Whether Biological/Adopted
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]		[redacted]

8. Identify the name and age of any person who currently resides with you and their relationship to you:

[redacted]

9. Identify the name and age of any person who has resided with you at any point over the past ten (10) years:

[redacted]

10. Identify all secondary and post-secondary schools you attended, starting with high school, and please provide the following information with respect to each:

Name of School	Address	Dates of Attendance	Degree Awarded	Major or Primary Field of Study
[redacted]	[redacted]	[redacted]	Diploma	General

			None (withdrew to care for family)	

11. Please provide the following information for your employment history over the past 10 years up until the present:

Employer Name	Address	Job Title/Description of Duties	Dates of Employment	Salary/Rate of Pay
l	Mall Blvd., Savannah, GA	Cashier, food preparation	March 2007 - 2010	
	Chatham County, GA	Janitor	Approximately 2013 - 2015	

12. Have you ever served in any branch of the military? Yes No

If Yes, please provide the following information:

(a) Branch and dates of service, rank upon discharge, and type of discharge received:

_____

(b) Were you discharged from the military at any time for any reason relating to your medical, physical, or psychiatric condition? Yes No

If Yes, state what that condition was: _____

_____

13. Within the last ten years, have you been convicted of, or plead guilty to, a felony and/or crime of fraud or dishonesty? Yes No

If Yes, please set forth where and when and identify the felony and/or crime:

_____

_____

14. Before contacting any attorney regarding this lawsuit or claim, had you ever seen any television or print advertisements regarding possible claims against inferior Vena Cava Filter manufacturers? ☐Yes ☒ No

If Yes, set forth the approximate date and nature of any such advertisement, whether the advertisement included the name of a law firm, whether the advertisement specifically mentioned C. R. Bard, Inc., Bard Peripheral Vascular, Inc., or "Bard", and other details that you recall. _____

II. CLAIM INFORMATION

1. Have you ever received a Bard Inferior Vena Cava Filter? ☒Yes ☐ No

If Yes, please check the box(es) for each type of Bard Inferior Vena Cava Filter you have received:

- ☐ Recovery®
- ☐ G2®
- ☐ G2®X
- ☐ G2®Express
- ☒ Eclipse®
- ☐ Meridian®
- ☐ Denali®
- ☐ Simon Nitinol
- ☐ Other (please identify): _____

2. For each Bard Inferior Vena Cava Filter identified above, please provide the following information:

(a) The date each Bard Inferior Vena Cava Filter was implanted in you: [redacted] _____

(b) The product code and lot number of each Bard Inferior Vena Cava Filter implanted in you: [redacted]

(c) Current location of the Bard Inferior Vena Cava Filter, including any portion thereof, if known: [redacted]

3. Describe your understanding of the medical condition for which you received the Bard Inferior Vena Cava Filter(s): [redacted]

4. Give the name and address of the doctor who implanted the Bard Inferior Vena Cava Filter(s): [redacted]

5. Give the name and address of the hospital or other healthcare facility where the Bard Inferior Vena Cava Filter was implanted: [redacted]

6. Have you ever been implanted with any other vena cava filters or related product(s) besides the Bard Inferior Vena Cava Filter(s) for the treatment of the same or similar condition(s) identified in your response to question 3 above? [redacted] Yes [redacted] No

If Yes:

(a) Please identify any such device(s) or product(s). _____

(b) When was this device or product implanted in you? _____

(c) Did the implantation take place before, at the same time, or after the procedure during which you were implanted with a Bard Inferior Vena Cava Filter?

(d) Who was the physician who implanted this other device or product?

(e) At what hospital or facility was this other device or product implanted in you?

(f) Why was this other device or product implanted in you?

7. Other than the Bard Inferior Vena Cava Filter device that is the subject of your lawsuit or identified in response to question 6 above, are you aware of any other Vena Cava Filter(s) implanted inside your body at any time? [redacted]Yes [redacted]No

If yes, please provide the following information:

(a) Product name: _____

(b) Date of procedure placing it and name and address of doctor who placed it:

(c) Condition sought to be treated through placement of the device:

(d) Any complications you encountered with the medical product or procedure:

(e) Does that product remain implanted inside of you today? ☐Yes ☐ No

8. Prior to implantation with a Bard Inferior Vena Cava Filter, did you receive any written and/or verbal information or instructions regarding the Bard Inferior Vena Cava Filter, including any risks or complications that might be associated with the use of the same?

[redacted]Yes [redacted]No Don't Know_____

If Yes:

(a) Provide the date you received the written and/or verbal information or instructions:

[redacted]

(b) Identify by name and address the person(s) who provided the information and instructions:

[redacted]

(c) What information or instructions did you receive?

(d) If you have copies of the written information or instructions you received, please attach copies to your response.

(e) Were you told of any potential complications from the implantation of the Bard Inferior Vena Cava Filter(s)? [redacted]Yes [redacted]No Don't Know _____

(f) If yes to (e), by whom?

(g) If yes to (e), what potential complications were described to you?

9. Do you believe that the Bard Inferior Vena Cava Filter(s) remains implanted in you?

[redacted] es [redacted]No Don't Know _____

If Yes:

(a) Has any doctor recommended removal of the Bard Inferior Vena Cava Filter(s)?

[redacted]Yes [redacted]No

If Yes:

(i) Identify by name and address every doctor who recommended removal of the Bard Inferior Vena Cava Filter(s): [redacted]

(ii) For each doctor identified in response to question 8(a)(i) above, state your understanding of why the doctor recommended removal. [redacted]

(iii) For each doctor identified in response to question 8(a)(i) above, state when the doctor recommended removal. [redacted]

10. Has the Bard Inferior Vena Cava Filter(s) implanted in you been removed, in whole or in part?

[redacted]es [redacted]No Don't Know_____

If Yes:

(a) Where, when, and by whom was the Bard Inferior Vena Cava Filter(s), or any portion of it, removed? [redacted]

(b) What portion of the Bard Inferior Vena Cava Filter(s) was removed on the date indicated in response to question 9(a) above? [redacted]

(c) Please check all that apply regarding the removal procedure(s):

[redacted] Removed percutaneously
Removed via an open abdominal procedure
Removed via an open chest procedure
Other, Describe: _____
Unknown

(d) Does any portion of the Bard Inferior Vena Cava Filter(s) remain implanted in you? [redacted]Yes [redacted]No Don't Know _____

If Yes, explain what portion of the Bard Inferior Vena Cava Filter(s) you believe is still implanted in you: [redacted]

(e) Explain why you consented to have the Bard Inferior Vena Cava Filter(s), or any portion thereof, removed? [redacted]

_____

_____

(f) Does any medical provider, physician, entity, or anyone else acting on your behalf have possession of any portion of the Bard Inferior Vena Cava Filter that was previously implanted in you and subsequently removed?

☐Yes ☐ No Don't Know__X___

If Yes, please state the name and address of the person or entity having possession of same._____

_____

11. Has any doctor or healthcare provider unsuccessfully attempted to remove the Bard Inferior Vena Cava Filter(s) implanted in you?

[redacted]es [redacted]No Don't Know_____

If Yes:

(a) How many attempts have been made to remove the Bard Inferior Vena Cava Filter(s) implanted in you?_____

(b) Provide the name and address of the doctor who removed (or attempted to remove) the filter strut(s) and the hospital or medical facility at which it was removed (or attempted to be removed).

Filter Removal/Attempted Removal #1

Doctor:_____

Hospital/Medical Facility:_____

Date:_____

Filter Removal/Attempted Removal #2

Doctor:_____

Hospital/Medical Facility:_____

Date:_____

Filter Removal/Attempted Removal #3

Doctor:_____

Hospital/Medical Facility:_____

Date:_____

(c) Please check all that apply regarding attempted removal procedure #1:

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe: _____

_____

☐ Unknown

(d) Please check all that apply regarding attempted removal procedure #2:

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe: _____

_____

☐ Unknown

(e) Please check all that apply regarding attempted removal procedure #3:

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe: _____

_____

☐ Unknown

12. Do you claim that your Bard Inferior Vena Cava Filter(s) fractured?

[redacted]Yes [redacted]No

If Yes:

(i) Please state the number of fractured struts retained in your body?

[redacted]_____

(ii) Please identify the location(s) within your body of each retained filter strut.

[redacted]

(iii) Please provide the date or approximate date when you were first informed of each fractured strut.

[redacted]

(iv) Has any health care provider recommended to you that a retained filter strut(s) should be removed?

[redacted]Yes [redacted]No

If Yes, provide the name and address of any such healthcare provider, as well as the approximate date on which the communication occurred.

(v) Has any health care provider recommended to you that a retained filter strut should <u>not</u> be removed?

[redacted]Yes [redacted]No

If Yes, provide the name and address of any such healthcare provider, as well as the approximate date on which the communication occurred.

[redacted]

(vi) Have any fractured struts been removed, or attempted to have been removed, from your body?

[redacted]Yes [redacted] No

If Yes:

(1) If any fractured filter strut has been removed (or a doctor has attempted to remove any strut), please check all that apply regarding the removal/attempted removal procedure(s):

☐ Removed percutaneously

☐ Removed via an open abdominal procedure

☐ Removed via an open chest procedure

☐ Attempted but unsuccessful percutaneous removal procedure

☐ Attempted but unsuccessful open abdominal procedure

☐ Attempted but unsuccessful open chest procedure

☐ Other, Describe: _____

☐ Unknown

(2) Provide the name and address of the doctor who removed (or attempted to remove) the filter strut(s) and the hospital or medical facility at which it was removed (or attempted to be removed).

Filter *Strut* Removal/Attempted Removal #1

Doctor:_____

Hospital/Medical Facility:_____

Date:_____

Filter *Strut* Removal/Attempted Removal #2

Doctor:_____

Hospital/Medical Facility:_____

Date:_____

13. Do you claim that you suffered bodily injuries as a result of the implantation of the Bard Inferior Vena Cava Filter(s)? [redacted] Yes [redacted] No

If Yes:

(a) Describe the bodily injuries, including any emotional or psychological injuries that you claim resulted from the implantation, attempted removal and/or removal

of the Bard Inferior Vena Cava Filter(s)?_[redacted]

(b) When was the first time you experienced symptoms of any of the bodily injuries you claim in your lawsuit to have resulted from the Bard Inferior Vena Cava Filter(s)?

_[redacted]

(c) When did you first attribute these bodily injuries to the Bard Inferior Vena Cava Filter(s)? _[redacted]

(d) To the best of your knowledge and recollection, please state the approximate date when you first saw a health care provider for any of the bodily injuries, or symptoms related thereto, you claim to have experienced related to the Bard Inferior Vena Cava Filter(s)?

[redacted]

(e) To the best of your knowledge and recollection, has any health care provider ever told you orally or in writing that any symptoms related to bodily injury are related to the Bard Inferior Vena Cava Filter(s)?

[redacted] es [redacted] No

If Yes, please state the name and address of any such health care provider, as well as providing the approximate date the statement was made, and provide the details of the communication: [redacted]

(f) Are you currently experiencing symptoms related to your claimed bodily injuries?

[redacted] es [redacted] No

If Yes, please describe your symptoms in detail:

[redacted]

(g) Are you currently seeing, or have you ever seen, a doctor or healthcare provider for any of the bodily injuries or symptoms listed above?

[redacted] es [redacted] No

If Yes, please list all doctors you have seen for treatment of any of the bodily injuries you have listed above.

Provider Name and Address	Condition Treated	Approximate Dates of Treatment
[redacted]	Broken IVC	[redacted]
[redacted]	Broken IVC	[redacted]
[redacted]	Broken IVC	[redacted]

h) Were you hospitalized at any time for the bodily injuries you listed above?

[redacted] Yes [redacted] No

If Yes, please provide the following:

Hospital Name and Address	Condition Treated	Approximate Dates of Treatment
[redacted]	[redacted]	[redacted]

14. Are you making a claim for lost wages or lost earning capacity?

[redacted] es [redacted] No

(a) If yes, state the annual gross income derived from your employment for each year, beginning five (5) years prior to the implantation of the Bard Inferior Vena Cava Filter(s) until the present: _____

_____

_____

(b) If yes, for what period of time are you claiming lost wages?_____

_____

_____

(c) If you are claiming lost earning capacity, do you claim that you have a claim for future lost wages?

☐Yes ☐ No

If yes, for what period of time do you claim you have lost future wages?

_____

_____

_____

15. Are you making a claim for lost out-of-pocket expenses? [redacted]Yes [redacted] No

If yes, please identify and itemize all out-of-pocket expenses you have incurred.

[redacted]o

[redacted]_____

_____

16. Has anyone filed a loss of consortium claim in connection with your lawsuit regarding the Bard Inferior Vena Cava Filter(s)?

[redacted]Yes [redacted] No

If yes, identify by name and address the person who filed the loss of consortium claim ("Consortium Plaintiff") and state the relationship of that person to you and state the specific nature of the Consortium Plaintiff's claim. Alfred Jones, Sr., Husband.

_____

_____

_____

17. Please indicate whether the Consortium Plaintiff alleges any of the damages set forth below:

Claims	Yes/No
Loss of services of spouse	[redacted]
Impaired sexual relations	[redacted]
Lost wages/lost earning capacity	[redacted]
Lost out-of-pocket expenses	[redacted]
Physical injuries	[redacted]
Psychological injuries/emotional injuries	[redacted]
Other	

18. Please list the name and address of any healthcare providers the Consortium Plaintiff has sought treatment for any physical, emotional, or psychological injuries or symptoms alleged to be related to his/her claim._____

[redacted]

19. Have you or anyone acting on your behalf had any communication, oral or written, with any of the Bard Defendants and/or their representatives?

[redacted]Yes [redacted]No Don't Know _____

If yes, set forth: (a) the date of any communication, (b) the method of communication, (c) the name of the person with whom you communicated, and (d) the substance of the communications._____

_____

_____

III. MEDICAL BACKGROUND

1. Provide your current: Age [redacted] Height [redacted] Weight [redacted]

2. Provide your: Age [redacted] Weight _[redacted]_ (approximate, if unknown) at the time the Bard Inferior Vena Cava Filter was implanted in you.

3. In chronological order, list any and all surgeries, procedures and/or hospitalizations you had in the ten (10) year period BEFORE implantation of the Bard Inferior Vena Cava Filter(s). Identify by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

Approximate Date	Description of Surgery or Hospitalization	Doctor or Healthcare Provider Involved (including address)
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	

[Attach additional sheets as necessary to provide the same information for any and all surgeries and hospitalizations leading up to the implantation of the Bard Inferior Vena Cava Filter.]

4. In chronological order, list any and all surgeries, procedures and/or hospitalizations you had AFTER implantation of the Bard Inferior Vena Cava Filter(s). Identify by name and address the doctor(s), hospital(s) or other healthcare provider(s) involved with each surgery or procedure; and provide the approximate date(s) for each:

Approximate Date	Description of Surgery or Hospitalization	Doctor or Healthcare Provider Involved (including address)
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	

[Attach additional sheets as necessary to provide the same information for any and all surgeries and hospitalizations after the implantation of the Bard Inferior Vena Cava Filter.]

5. To the extent not already provided in the charts above, provide the name, address, and telephone number of every doctor, hospital or other health care provider from which you have received medical advice and/or treatment from ten (10) years before the date the filter was implanted to the present:

Name and Specialty	Address	Approximate Date/Years of Visits
All care provided by the hospitals listed above.		

6. *Before the implantation* of the Bard Inferior Vena Cava Filter(s), did you regularly exercise or participate in activities that required lifting or strenuous physical activity? (Please include all physical activities associated with daily living, physical fitness, household tasks, and employment-related activities.)

Yes [redacted] No [redacted]

If yes, please describe each activity in detail. [redacted]

7. *Since the implantation* of the Bard Inferior Vena Cava Filter(s), have you regularly exercised or participated in activities that required lifting or strenuous physical activity?

(Please describe all range of physical activities associated with daily living, physical fitness, household tasks, and employment-related activities.)

[redacted]Yes [redacted]No

If yes, please describe each activity in detail. [redacted]

8. During the past ten (10) years, what have been your primary hobbies or recreational activities? [redacted]

(a) Do you claim that you are unable to participate in any of the hobbies or recreational activities listed in response to question 8 above as a result of you having been implanted with a Bard Inferior Vena Cava Filter(s)?

[redacted]Yes [redacted]No

(b) If yes, what hobbies or recreational activities do you claim that you are unable to participate in as a result of having been implanted with a Bard Inferior Vena Cava Filter(s)? [redacted].

(c) For what period of time do you claim that you were or have been unable to participate in any hobbies or recreational activities as a result of having been implanted with a Bard Inferior Vena Cava Filter(s)? [redacted]

9. To the best of your knowledge, have you ever been told by a doctor or another health care provider that you have suffered, may have suffered, or presently do suffer from any of the following:

[redacted]
Lupus
Crohn's Disease
Factor V Leiden
Protein Deficiency

[redacted] Spinal Fusion or Other Back Procedures
Anti-thrombin Deficiency
Prothrombin Mutation
Deep Vein Thrombosis
Pulmonary Embolism
Auto Immune Disorder
Varicose Veins
Heart Procedures
Blood Disorder
Please Describe: [redacted]_____

[redacted] Bariatric Surgery
Anticoagulation Medication (e.g., Coumadin, Warfarin, etc.)
Ulcerative Colitis/Inflammatory Bowel Disease (IBD)
Cancer
Please Describe:_____

* * * * * * * * * *

THE FOLLOWING QUESTIONS ARE CONFIDENTIAL AND SUBJECT TO THE PROTECTIVE ORDER APPLICABLE TO THIS CASE.

(A) Have you been diagnosed with and/or treated for any drug, alcohol, chemical and/or other addiction or dependency during the five (5) years prior to the filing of this lawsuit through the present? [redacted]Yes [redacted] No

If yes, specify type and time period of dependency, type of treatment received, name of treatment provider, and current status of condition:

_____

_____

_____

_____

(B) Have you experienced, been diagnosed with or received psychiatric or psychological treatment of any type, including therapy, for any mental health conditions including depression, anxiety, or other emotional or psychiatric

disorders during the five (5) years prior to the filing of this lawsuit through the present? [redacted] Yes [redacted] No

If yes, specify condition, date of onset, medication/treatment, treating physician and current status of condition:

_____

_____

_____

_____

* * * * * * * * * *

10. Do you now or have you ever smoked tobacco products? [redacted] Yes [redacted] No

If yes:

How long have/did you smoke? [redacted] _____

12. List each prescription medication you have taken for more than three (3) months at a time during the timeframe beginning five (5) years prior to implantation of the Bard Inferior Vena Cava Filter and continuing to the present, giving the name and address of the pharmacy where you received/filled the medication, the reason you took the medication, and the approximate dates of use.

Medication and Dosage	Prescribing Physician	Pharmacy Name and Address	Reason for Taking Medication	Approximate Date(s) of Use

IV. INSURANCE INFORMATION

1. Provide the following information for any past or present medical insurance coverage from the timeframe beginning five (5) years prior to implantation of the Bard Inferior Vena Cava Filter and continuing to the present:

Insurance Company Name and Address	Policy Number	Name of Policy Holder/Insured (if different than yourself)	Approximate Dates of Coverage

2. To the best of your knowledge, have you ever been approved to receive or are you currently receiving Medicare/Medicaid benefits due to age, disability, condition, or any other reason or basis?

[redacted]es [redacted]No

If yes, please specify the date on which you first became eligible:_____

[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]

V. PRIOR CLAIM INFORMATION

1. Have you filed a lawsuit or made a claim in the last ten (10) years, other than in the present suit relating to any bodily injury?

[redacted]Yes [redacted]No

If yes, please specify the following:

(a) Court in which the lawsuit/claim was filed or initiated:_____

_____

(b) Case/Claim Number:_____

(c) Nature of Claim/Injury:_____

_____

2. Have you ever applied for Workers' Compensation (WC), Social Security disability (SSI or SSD) benefits, or other State or Federal disability benefits?

[redacted]Yes [redacted]No

If yes, please specify the following:

(a) Date (or year) of application: _____

(b) Type of benefits sought: [redacted]

(c) Agency/Insurer from which you sought the benefits: [redacted]

(d) Nature of the claimed injury/disability: [redacted]

(e) Whether the claim was accepted or denied: [redacted]

VI. FACT WITNESSES

1. Identify by name, address, and relationship to you, all persons (other than your healthcare providers) who possess information concerning your injuries and/or current medical condition:

Name	Address	Relationship to You	Information You Believe Person Possesses
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

VII. IDENTIFICATION OF DOCUMENTS AND OTHER ELECTRONICALLY STORED INFORMATION

For the period beginning three (3) years prior to the implantation of the Bard Inferior Vena Cava Filter until the present, please identify all research, including on-line research, that you conducted regarding the medical complaints or condition for which you received the Bard Inferior Vena Cava Filter (pulmonary thromboembolism, anticoagulant therapy, etc.) Identify the date, time, and source, including any websites visited. (Research conducted subsequent to and for the purpose of understanding the legal and strategic advice of your counsel is not considered responsive to this request.)

None.

VIII. DOCUMENT REQUESTS

1. RELEASES.

NOTE: Please sign and attach to this Fact Sheet the authorizations for the release of records appended hereto.

2. DOCUMENTS. State whether you have any of the following documents in your possession, custody, and/or control. If you do, please provide a true and correct copy of any such documents with this completed Fact Sheet. Please ensure that the production of documentation includes specific reference to the questions to which the document is provided in response.

(a) If you were appointed by a Court to represent the plaintiff in this lawsuit, produce any documents demonstrating such appointment.

(i) Not applicable _____X_____

(ii) The documents are attached_____ [OR] I have no documents_____

(b) If you represent the Estate of a deceased person in this lawsuit, produce a copy of the decedent's death certificate and autopsy report (if applicable).

(i) Not applicable_____X_____

(ii) The documents are attached_____ [OR] I have no documents_____

(c) Produce each and every medical record of each and every medical facility, pharmacy, or practitioner of the healing arts identified by you in response to the questions in Sections II and III above regarding your medical care and history for the time period beginning ten (10) years prior to the implantation of the Bard Inferior Vena Cava Filter and continuing to the present.

(i) Not applicable_____

(ii) The documents are attached__X___ [OR] I have no documents_____

Plaintiff is producing all such records in her possession and will supplement as additional records become available.

(d) Produce any communication (sent or received) in your possession, which shall include materials accessible to you from any computer on which you have sent or received such communications, concerning the Bard Inferior Vena Cava Filter(s) or subject of this litigation, including, but not limited to all letters, emails, blogs, Facebook posts, Tweets, newsletters, etc. sent or received by you. (Research conducted subsequent to and to understand the legal and strategic advice of your counsel is not considered responsive to this request.)

(i) Not applicable__X___

(ii) The documents are attached_____ [OR] I have no documents_____

(e) Produce all documents, including journal entries, lists, memoranda, notes, diaries, photographs, video, DVDs or other media, discussing or referencing the Bard Inferior Vena Cava Filter(s), the injuries and/or damages you claim resulted from the Bard Inferior Vena Cava Filter(s), and/or evidencing your physical condition from three (3) years prior to the implantation of the Bard Inferior Vena Cava Filter(s) to present. (Research conducted subsequent to and to understand the legal and strategic advice of your counsel is not considered responsive to this request.)

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(f) Produce any Bard Inferior Vena Cava Filer product packaging, labeling, advertising, or any other product-related items in your possession, custody or control.

(i) Not applicable__X___

(ii) The documents are attached_____ [OR] I have no documents_____

(g) Produce all documents concerning any communication between you, your attorney(s), your agent(s), your expert(s), or your representative(s) and the Food and Drug Administration (FDA), or between you and any employee or agent of the Bard Defendants, regarding Bard Inferior Vena Cava Filters.

(i) Not applicable__X___

(ii) The documents are attached_____ [OR] I have no documents_____

(h) Produce all documents that you, your attorney(s), your agent(s), your expert(s), or your representative(s) provided to the Food and Drug Administration (FDA)

and/or the Department of Health and Human Services regarding Bard Inferior Vena Cava Filters.

(i) Not applicable__X___

(ii) The documents are attached_____ [OR] I have no documents_____

(i) Produce all documents concerning any communication between you, your attorney(s), your agent(s), your expert(s), or your representative(s) with anyone at any television station, radio station, newspaper, periodical, magazine, weblog, internet website, or any other media outlet regarding Bard Inferior Vena Cava Filters.

(i) Not applicable__X___

(ii) The documents are attached_____ [OR] I have no documents_____

(j) Produce all documents that you, your attorney(s), your agent(s), your expert(s), or your representative(s) provided to anyone at any television station, radio station, newspaper, periodical, magazine, weblog, internet website, or any other media outlet regarding Bard Inferior Vena Cava Filters.

(i) Not applicable__X___

(ii) The documents are attached_____ [OR] I have no documents_____

(k) Produce all documents in your possession, custody, or control evidencing or relating to any correspondence or communication between C. R. Bard, Inc. or Bard Peripheral Vascular, Inc. (or any related companies or divisions) and any of your doctors, healthcare providers, and/or you relating to Bard Inferior Vena Cava Filters, except as to those communications which are protected by the attorney-client privilege or attorney work product doctrine.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents__X___

(l) Produce all documents in your possession, custody, or control reflecting, describing, or in any way relating to any instructions or warnings you received prior to implantation of any Inferior Vena Cava Filter(s) concerning the risks and/or benefits associated with Inferior Vena Cava Filter(s), including but not limited to the Bard Inferior Vena Cava Filter implanted in you.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents__X___

(m) Produce any and all documents reflecting the model number and lot number of the Bard Inferior Vena Cava Filter(s) you received.

(i) Not applicable_____

(ii) The documents are attached__X___ [OR] I have no documents_____

(n) If you underwent surgery or any other procedure to remove, in whole or in part, the Bard Inferior Vena Cava Filter(s), produce any and all documents, other than documents that may have been generated by expert witnesses retained by your counsel for litigation purposes, that relate to any evaluation of the Bard Inferior Vena Cava Filter(s) removed from you.

(i) Not applicable_____

(ii) The documents are attached Will Supplement

[OR] I have no documents_____

(o) If you claim lost wages or lost earning capacity, produce copies of your Federal and State tax returns for the five (5) years prior to implantation of the Bard Inferior Vena Cava Filter(s) to the present redacting irrelevant information.

(i) Not applicable_____

(ii) The documents are attached_____ [OR] I have no documents_____

(p) Produce all documents in your possession, custody, or control concerning payment by Medicare on behalf of the injured party and relating to the injuries claimed in this lawsuit. This includes, but is not limited to Interim Conditional Payment summaries and/or estimates prepared by Medicare or its representatives regarding payments made on your behalf for medical expenses relating to the subject of this litigation.

(i) Not applicable__X___

(ii) The documents are attached_____ [OR] I have no documents_____

[Please note: if you are not currently a Medicare-eligible beneficiary, but become eligible for Medicare during the pendency of this lawsuit, you must supplement your response at that time. This information is necessary for all parties to comply with Medicare regulations. See 42 U.S.C. 1395y(b)(8), also known as Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 and 42 U.S.C. 1395y(b)(2) also known as the Medicare Secondary Payer Act.]

(q) Produce all screenshots of all webpages of each type of social media used by you (including, but not limited to, Facebook, Twitter, Instagram, Vine, Snapchat, YouTube, LinkedIn) showing any and all "posts" and/or "messages" from the date of implantation to the present.

(i) Not applicable__X___

(ii) The documents are attached_____ [OR] I have no documents_____

(r) Produce the Bard Inferior Vena Cava Filter(s) or any and all components thereof previously implanted in you.

VERIFICATION

I, Doris Jones, declare under penalty of perjury, subject to all applicable laws and in the presence of the below named witness, that I have carefully reviewed the final copy of this Plaintiff Fact Sheet dated _____ and verified that all of the information provided is true and correct to the best of my knowledge, information and belief.

_____
Signature of Witness

_____
Name of Witness

_____
Address of Witness

Doris Jones
Signature of Plaintiff

5549105v1/26997-0000

VERIFICATION

I, _____, declare under penalty of perjury, subject to all applicable laws and in the presence of the below named witness, that I have carefully reviewed the final copy of this Plaintiff Fact Sheet dated _____ and verified that all of the information provided is true and correct to the best of my knowledge, information and belief.

Signature of Witness

Alfred L. Jones Sr.
Name of Witness

Same As Plaint. AC
Address of Witness

_____
Signature of Plaintiff

REDACTED DOCUMENTS RELATED TO DOCKET 7351

Exhibit B - Filed Redacted

REDACTED DOCUMENTS RELATED TO DOCKET 7351

Exhibit D - Filed Redacted

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS) Case No.
PRODUCTS LIABILITY LITIGATION) MD-15-02641-PHX-DGC

DO NOT DISCLOSE

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF ANTHONY JAMES AVINO, M.D.

March 23, 2017

Savannah, Georgia

4:06 p.m.

Reported by: Karen Kidwell, RMR, CRR

GOLKOW TECHNOLOGIES, INC.

877.370.3377 ph | 917.591.5672 fax

deps@golkow.com

So why don't we start by introducing yourself to the jury.

A. Okay. Anthony Avino. I'm a board-certified vascular surgeon. I've been in Savannah since I finished my training in 1999. Born in New York, grew up in Florida. Went to Vanderbilt, went to University of Florida, and then did my vascular at Mayo Clinic and the University of Florida, and been in Savannah ever since in practice, the full gamut of vascular surgery.

Married with three kids. And that's my whole life.

Q. Good.

A. In two lines or less.

Q. So let's break that down a little bit. Where did you go to undergrad?

A. Vanderbilt.

Q. And then medical school?

A. University of Florida.

Q. What year did you graduate?

A. From college in '87.

Q. Okay.

A. And from medical school in '91.

Q. And then after medical school, you did a residency?

you intended to go, because of confusing anatomy; or that the filter migrates from the position you want it; or that it tilts at an angle that you don't want it so it doesn't completely cover the vein or might later be hard to remove; or that either part of the filter breaks off and travels somewhere else; or that even the whole device can break off and migrate to a position that you don't want it to go.

Or that this filter -- all the filters have, by necessity of design, have legs that have some force to hold it into position in the wall, and sometimes they can work their way all the way through the wall of the vein into adjacent structures, like the intestine, or even the artery -- adjacent artery.

Q. When did you -- you talked about that 10, 15 years ago you were doing IVC filters. Do you remember when you started implanting IVC filters? You, personally.

A. Well, from beginning of my residency. So -- you know, certainly from day 1, when I arrived here. So I've always -- I've always implanted them. You know, in training, and then the whole time I've been here. So there wasn't any certain time, because I've always -- it's something you start doing early in your training, and then it just never stops.

out of an IFU, cautiously, and just have become standard of care.

There's lots of examples of things we still use appropriately that might not be in the IFU. But, in general, we certainly consider the IFU, and -- because that's what the research was done on for certain devices, and that's what the FDA is recommending, and that's what the company -- and typically, that's very strongly what the company recommends.

Q. And do you read the IFU?

A. Sometimes. I mean, I have read them. I don't -- certainly don't read them on every package, because they're the same from the same device, but -- you know, not -- not all the time, but it does come up, for example, at meetings, or you're reading about and someone's discussing an issue with an IFU. You know, if something is within the IFU or not, to help define things that might be outside of the IFU but still medically indicated.

Q. Do you know if you ever read the IFU for the Eclipse IVC filter?

A. Not that I recall.

Q. Okay. And IFUs have warnings on them of side effects, complications, things like that, also?

A. Yes.

Q. And even if you haven't read the Eclipse IFU, you're probably generally familiar with IVC filter IFUs, if they warn of things like fractures, migration, perforation, tilt; complications like that. Right?

A. Yes. Yes.

Q. But is it your understanding these complications are rare, for IVC filters?

A. Well, depends how you define "rare." I mean, back -- originally, when we were implanting filters 15, 20 years ago, everyone thought they were rare.

Now people think they're -- reached a peak, and reached a peak in frequency, and then we think that now they're -- they're less frequent than they were before. So it's been a migrating target in terms of what the risks are or what our understanding of the risks are.

Q. If you can recall your mindset in [redacted] what was your understanding of the rarity of complications from IVC filters then?

A. [redacted]

[redacted]

Q. And so essentially [redacted]

[redacted]

A. [redacted]

[redacted]

[redacted]

So there's some advantages to having a retrievable filter, if you, even if you think it's going to stay in long term.

Q. Right, but certainly [redacted]; that was the intent?

A. Yes.

Q. And then around that same section we were just looking at there, maybe the same sentence, there, in the indications, [redacted]

[redacted]

[redacted]

[redacted]

Do you recall that -- anything about that discussion? I don't imagine you do, [redacted]

[redacted]

A. [redacted]

Q. Is that just kind of a general note you would typically put in there?

A. [redacted]

Q. And I want to ask about a little bit -- a different portion of that sentence, though. Is it possible that the discussion was with -- more with [redacted]?

A. [redacted]

Q. Okay.

A. [redacted]

Q. And that would be your practice, right?

MR. COMBS: 1287.

THE WITNESS: Oh, okay. Sorry. Not going by the exhibit number. Okay.

BY MS. DALY:

Q. Yeah. You got 1287?

A. I do.

Q. And it's 4017, we've called that exhibit. Sorry.

A. Yes.

Q. All right. Sorry. So can you describe for me what is meant by -- under the indications, where it says. [redacted] What does that mean?

A. [redacted].

Q. That may have been a transcription issue?

A. Yeah, because [redacted] is not -- that's a general laymen's term I wouldn't have used in there.

Q. So we can take that out, and just call it [redacted]?

A. Yeah, [redacted]

[redacted]

Q. Okay. And then it goes on to say [redacted]

[redacted]

[redacted]

And then again, [redacted]

[redacted]

A. [redacted]

[redacted]

Q. Okay.

A. [redacted]

[redacted]

[redacted]

[redacted]

MS. DALY: Okay. We will mark this 4027, because -- I don't think you have these pages. These are marked at the bottom of the pages.

(Exhibit 4027 was marked for identification.)

BY MS. DALY:

Q. MDR453, 454 and 455, if you'd look at those. [redacted]

[redacted]

[redacted]. Do you see that?

A. Yes.

Q. Are these -- [redacted]

[redacted]

A. [redacted].

Q. [redacted]

[redacted]

A. [redacted]

Q. All right. So if you would look for me at -- [redacted],

[redacted]

[redacted]

[redacted].

A. [redacted]

[redacted]

Q. Then it talks about [redacted]

[redacted] is that right?

A. [redacted]

Q. And then it says that [redacted]

[redacted]

A. [redacted]

Q. What are those?

A. [redacted]

[redacted]

Q. [redacted]

[redacted]

A. [redacted]

Q. It goes on to say: [redacted] --

[redacted]

Do you see that?

A. [redacted]

Q. All right. Is there any -- is there any relevance to the [redacted]

[redacted]

A. [redacted]

Q. And what's the relevance?

A. Well, [redacted]

[redacted]

Q. [redacted]

[redacted]

A. [redacted].

Q. Would that be another reason [redacted]

[redacted]

A. [redacted]

REDACTED DOCUMENTS RELATED TO DOCKET 7351

Exhibit E - Filed Redacted

Exhibit E

Deposition of:

Derek Muehrcke , M.D.

July 24, 2017

In the Matter of:

In Re: Bard IVC Filters Products Liability

Veritext Legal Solutions
1075 Peachtree St. NE , Suite 3625
Atlanta, GA, 30309
800.808.4958 | calendar-atl@veritext.com | 770.343.9696

Q What about Janet Hudnall?
A Just that, you know, she felt that a lot was not known about the BARD filter, the Recovery filter when it was initiated, and a lot still wasn't known, and that it was kind of cleared and sold without a lot of knowledge about it.
Q What about Chris Ganser?
A I can't remember specifics about that.
Q What about Steven Williamson?
A Steven Williamson. Oh, 42. I can't remember specifics. Nothing specific.
Q Have you ever asked the plaintiffs' attorneys for the opportunity -- well, strike that.
Are you aware that more than 3 million pages of documents have been produced by BARD in this litigation?
A I've heard there's been millions, yeah.
Q And have you ever asked for the opportunity to review or search those documents?
MR. O'CONNOR: Form.
A I've never asked for the opportunity to search them, no.
Q Would you agree with me that all IVC filters have a risk of complications?
MR. O'CONNOR: Object to form.
A All IVC filters have a risk of complications,

yes.
Q That would include migration?
MR. O'CONNOR: Form.
A Well, I think that there's rates of migration, but they can -- they can migrate.
Q All filters can migrate; correct?
MR. O'CONNOR: Form.
A There are -- all filters can migrate, yes.
Q And all filters have the potential complication of fracture?
A Yes. That's true.
Q And all filters have the potential complication of tilt?
MR. O'CONNOR: Okay.
A Correct. Some are much less likely, the TrapEase, OptEase, but all can tilt.
Q What's the difference, if any, between the words penetration and perforation with regard to filters?
A That's a nuance for the radiologist to kind of get into. I think -- to a certain extent, to me they're synonymous, but I think they prefer the word penetration as opposed to perforation. Perforation, one of the BARD defense experts felt was a kind of a pejorative term implying that things were going to leak out all over the

place. And I think that the radiologists prefer penetration as opposed to perforation.

I think it's a distinction without a difference in my mind, but whatever.

Q Would you agree that all filters carry the risk of penetration --

MR. O'CONNOR: Form.

Q -- or perforation?

A Yes.

Q Looking at the [redacted], page 7, paragraph 2, you said: [redacted]

[redacted]

[redacted]

[redacted]

Is that correct?

A That's correct.

Q And would you agree that all filters have the potential to caudally migrate?

A I believe that there was an unacceptable safety profile for the -- for the G2 filter.

MR. O'CONNOR: Move to strike as nonresponsive.

Q My question was, do you agree that all filters have the potential to caudally migrate?

A All filters can migrate caudally.

MR. O'CONNOR: Late objection to the form of

filter, would expect that it absolutely would never have one of those complications. But your point, if I understand it correctly, is not that physicians don't expect there to be an occasional complication, it's that they don't expect the complications to occur at the rate you allege they do?

A It's more than that. Can I expound?

Q Yeah.

A The BARD filter has all these problems. The other filters have -- like, the TrapEase and OptEase have a problem with cable thrombosis. You know, the -- the -- the BARD filter not only has a higher rate of individual complication, but it has a lot more of several complications.

MR. NORTH: Move to strike as nonresponsive.

Q Do you believe that a physician implanting a BARD filter has an expectation that under no circumstances, in no scenario, no matter what happens, that filter will not migrate?

A Well, I think that's an unrealistic expectation.

MR. O'CONNOR: Form.

A I think that the filters can have problems.

Q And the same would be true as to tilt, perforation, or fracture?

MR. O'CONNOR: Form.

A Every filter can have a complication.

Q Have you had any discussions with Dr. Hurst about your work in this case?

A No.

Q Have you ever met Dr. Hurst?

A No.

Q With regard to [redacted]

[redacted]

A Oh, boy. Let me look at my notes here.

[redacted].

[redacted]

Q And did you independently do that when you were assessing the films, or did you rely on Dr. Hurst's measurements?

A No, I -- I -- I -- I did my own measurements. I mean, I -- I'm not a radiologist. I would defer to